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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,330	09/12/2005	Gary N. Mills	103477-0007	6689

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EXAMINER	
SZMAL, BRIAN SCOTT	
ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,330	MILLS ET AL.	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Amendment

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Objections

2. Claim 8 is objected to because of the following informalities: In line 4: "one or electrical currents" appears it should read as "one or more electrical currents". Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Rieke (3,452,743).

Rieke discloses a body impedance bridge and further discloses providing a first set of injection electrodes and a second set of measurement electrodes (see at least Figures 2-5); positioning members of the first set of electrodes on an external surface of the body to introduce electrical current flow through the tissue and thereby establish flow paths that define injection vectors along which electrical currents flow between two or more injection electrodes (see at least Figures 2-5); positioning members of the

second set of electrodes on the body to define measurement vectors relating to electrical voltages produced in response to the electrical currents flowing between the injection electrodes, the injection and measurement vectors defining an anatomical space of the tissue (see at least Figures 2-5); deriving from each of different pairs of the injection and measurement vectors two or more electrical bio-impedance value indicating the electrical bio-impedance of body tissues and fluids within a region of the anatomical space (see Column 1, lines 28-32); analyzing the two or more electrical bio-impedance values for indications of fluid movement, accumulation or depletion affecting the region (see Column 1, lines 28-32); each member of the first set includes a current source and a current sink, the current source and current sink being positioned at locations on the body such that electrical current flowing from a current source of one of the members flows into a current sink of another one of the members (see at least Figures 2-5; Column 6, lines 43-75 and Column 7, lines 1-6); each member of the first set includes multiple current sources and multiple current sinks, the current sources and current sinks being positioned at locations on the body such that electrical current flowing from a current source of one or more electrical currents flowing from current sources of more than one of the members flow into one or more current sinks of another one of the members (see at least Figure 4).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rieke (3,452,743) as applied to claim 1 above, and further in view of Takehara et al (2002/0022787 A1) in view of Duong et al (6,740,518 B1).

Rieke, as discussed above, disclose a means for measuring the body impedance of a subject but fail to disclose the electrical current flow is introduced at multiple signal frequencies and the analyzing of the electrical bioimpedance value includes Fourier analysis and data reduction.

Takehara et al disclose a means for measuring body water concentration via multi-frequency bioimpedance measurements and further disclose the electrical current flow is introduced at multiple signal frequencies. See Paragraphs 0039-0046.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Rieke to include the use of multi-frequency currents, as per the teachings of Takehara et al, since it would provide a means of more accurately determining any changes in the tissue impedance based on the increased applied current.

Rieke and Takehara et al however fail to disclose analyzing the acquired data through the use of Fourier transform and data reduction.

Duong et al disclose a means for detecting analytes and further disclose analyzing the acquired data through the use of Fourier transform and data reduction. See Column 86, lines 48-51; and Column 89, lines 1-21.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Rieke and Takehara et al to include the use of Fourier transform and data reduction, as per the teachings of Duong et al, since it is well known in the art to utilize data analysis methods such as Fourier transform and data reduction when dealing with acquired impedance measurements.

7. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rieke (3,452,743) as applied to claim 1 above, and further in view of Baura et al (6,561,986 B2).

Rieke, as discussed above, disclose an impedance means for determining the presence of congestive heart failure, but fails to disclose the electrical current flow is introduced by a complex electrical current waveform and the analyzing of the electrical bio-impedance value includes chirp transform analysis or waveform analysis.

Baura et al disclose a means for assessing hemodynamic parameters and further disclose the electrical current flow is introduced by a complex electrical current waveform and the analyzing of the electrical bio-impedance value includes chirp transform analysis or waveform analysis. See Figure 12; Column 19, lines 30-67; Column 20; and Column 21, lines 1-54.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Rieke to include waveform analysis of the acquired signals, as per the teachings of Baura et al, since it is well known in the art to utilize several different means for signal analysis, including waveform analysis.

8. Claims 4-6 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rieke (3,452,743) as applied to claim 1 above, and further in view of Alt (6,829,503 B2).

Rieke, as discussed above, disclose a means of measuring the impedance of a body but fail to disclose the analyzing of the electrical bio-impedance values entails determining differences in the electrical bio-impedance values derived from the injection and measurement vectors; determining temporal changes in the electrical bio-impedance values derived from the injection and measurement vectors; the analyzing of the electrical bio-impedance values entails determining temporal changes in the electrical bio-impedance values derived from the injection and measurement vectors; the injection and measurement vectors define a nominal shape of the anatomical space in the presence of a nominal quantity of fluid, and in which the presence of other than the nominal quantity of fluid changes the anatomical space from its nominal shape; analyzing the electrical bio-impedance values to determine the extent of fluid volume in the mammalian tissue; and the fluid includes blood, and further comprising analyzing the electrical bio-impedance values to determine whether the presence of a volume of blood indicates an accumulation or a loss of blood.

Alt discloses a congestive heart failure monitor and further discloses the analyzing of the electrical bio-impedance values entails determining differences in the electrical bio-impedance values derived from the injection and measurement vectors; determining temporal changes in the electrical bio-impedance values derived from the injection and measurement vectors; the analyzing of the electrical bio-impedance values

entails determining temporal changes in the electrical bio-impedance values derived from the injection and measurement vectors; the injection and measurement vectors define a nominal shape of the anatomical space in the presence of a nominal quantity of fluid, and in which the presence of other than the nominal quantity of fluid changes the anatomical space from its nominal shape; analyzing the electrical bio-impedance values to determine the extent of fluid volume in the mammalian tissue; and the fluid includes blood, and further comprising analyzing the electrical bio-impedance values to determine whether the presence of a volume of blood indicates an accumulation or a loss of blood. See whole document, in particular, Column 4, lines 30-47.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Rieke to include analyzing impedance values entails determining the difference in impedance values derived from the injection and measurement vectors or determining temporal changes in the impedance values, a change in shape of the nominal shape indicates an abnormal amount of fluid, analyzing the impedance values to determine the extent of fluid volume in the tissue, and determining if the volume indicates an accumulation or loss of blood, as per the teachings of Alt, since it would provide a means of utilizing the obtained impedance data to further determine the fluid parameters of a patient.

Response to Arguments

9. Applicant's arguments with respect to claims 1-11 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736